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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,455	11/06/2003	Eric B. Stenzel	12013/48301	8547

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EXAMINER

GBERBI, SUZETTE JAIME J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/701,455

Applicant(s)

STENZEL, ERIC B.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,9-17,19-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9-17,19-21 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/9/05 & 6/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment dated June 6/30/05 has been received in application serial number 10/701,455. claims 2-3, 6-8, 18, and 22 have been canceled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 4-5, 9-17, 19-21, 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
4. In particular claims 1, 12 and 17 recite subject matter that is not described in the specification or drawings specifically there is NO mention in the specification about a first set of pellets and a second set of pellets contained upon a structure. The specification describes individual pellets with individual coatings upon a structure in single form (being thick or thin) but nowhere does the specification disclose the arrangement of these pellets as a first set and second set upon a structure as claimed.

Applicant has stated in the remarks section that the claimed subject matter is described in several places in the specification...for example paragraph 40 on page 13, but it has been found that these passages merely describes individual pellets being made of various sizes depending upon the composition. It does not describe *depositing a set of second pellets on the structure at a second site*.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, *the second set of pellets deposited on the structure at a second site* must be shown or the feature(s) canceled from the claim(s). Please note the new matter rejection above.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4, 9-10, 12-16, 24-27 are rejected under 35 U.S.C. 103(a) as being obvious over Stoll 6,849,089. Stoll discloses the invention as claimed noting figures 6 and 7 comprising: A medical structure (2); a set of first coated pellets (**the coating is 5'''**), each of the first coated pellets containing at least one first therapeutic composition (**the round sphere micro-capsules equate to the claimed pellet. The first material 4 is the first therapeutic substance**) the set of first coated pellets deposited on the structure (**the claimed structure equates to element 2 main body**) at a first site for controlled delivery of at least one first therapeutic composition (**the first site can be interpreted as the first microspore or as the first layer upon the structure 2 as shown in figures 6 and 8) and a set of second coated pellets. (the second set of**

pellets can be interpreted as the adjacent pellets seen in figure 7 or as the second layer of pellets as shown in figures 6 and 8) each of the second coated pellets containing at least one second therapeutic composition (the second therapeutic composition is contained in the micro-sphere in a separate second compartment. The claim does not require a different second therapeutic substance), the set of second coated pellets deposited on the structure at a second site (as described above a second site can be interpreted broadly) for controlled delivery of the at least one second therapeutic composition to a desired location within the body; wherein each of said first coated pellets is covered with a first coating and each of said second coated pellets is covered with a second coating (they are both individually coated with polymers and the claim does not require different coatings); wherein each of the first coated pellets contains a substance in addition to the first therapeutic composition (this can be interpreted broadly because a “substance in addition to the first therapeutic composition” can simply be the make-up of the degradable polymer);

However Stoll does not specify: wherein the first coating is thinner than the second coatingsuch that each of the first coated pellets is substantially the same size as each of the second coated pellets. It would have been obvious to one having ordinary skill in the art at the time the invention was made that Stoll's invention contemplates to varying or modifying the thinness or thickness of the coatings of the micro-spheres/pellets in order to control the release rate of the agent(as indicated in col. 13, lines 18-33) and is deemed a design modification.

9. Claims 5, 11, 17, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoll in view of Bennett et al. 6,339,130. Stoll has been disclosed above however Stoll's adhesive is not described. Bennett et al. teaches that adhesives for use with prosthetic devices are well known and polymers are known adhesives with curing properties (see abstract and col. 3, lines 12-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the adhesive of Stoll with the claimed properties such as polymers because Bennett et al. teaches that they can be used with a variety of surgical devices. Stoll also does not specify that a plurality of sublayers on the micro-spheres. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a plurality of sublayers because Stoll does note that a plurality of layers are contemplated (see figure 5) in order to vary the degradation and release rate of the therapeutic compositions.

Response to Arguments

Applicant's arguments filed 6/30/05 have been fully considered but they are not persuasive. Applicant has amended the claims with subject matter not found or described in the specification. Applicant contends that Stoll does not disclose or suggest pellets having different coating thickness. The examiner has pointed out figure 7 where clearly illustrates that the walls (5'') have varying wall thicknesses. Applicant contends that that Stoll does not disclose an additional "substance". This terminology is

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broad and is being interpreted as any additional material. Therefor the substance in addition to the first therapeutic composition if the make-up of the bio-degradable polymer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

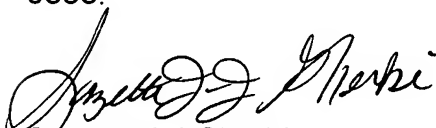
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

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The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

0858.

A handwritten signature in cursive script, appearing to read "Suzette J-J Gherbi".

Suzette J-J Gherbi
19 September 2005